

657—13.8 (155A) Record requirements.

13.8(1) *Production record.* A production record shall be prepared and kept for each drug product compounded for an individual patient. A production record is not required when mixing or reconstituting a drug according to the product's labeling or the manufacturer's directions. The record shall include the following information:

- a. Production date;
- b. List of ingredients and quantity of each ingredient used;
- c. Initials or unique identification of each person involved in each of the compounding steps;
- d. Initials or unique identification of each pharmacist verifying each of the compounding steps;
- e. Internal control or prescription number and, if the prescription is filled using a product compounded in bulk pursuant to rule 657—20.11(126), the internal control number assigned to the batch and recorded in the batch production record.

13.8(2) *Batch master formula record.* Pursuant to the provisions of 657—subrule 20.3(3), pharmacies may compound drugs in bulk quantities for subsequent prescription labeling and dispensing. For each drug product compounded in bulk quantity, a master formula record containing the following information shall be prepared:

- a. Name of the product;
- b. Specimen or copy of label;
- c. List of ingredients and quantities;
- d. Description of container used;
- e. Compounding instructions, procedures and specifications.

13.8(3) *Batch production record.* For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

- a. The information from the master formula record;
- b. Records of each step in the compounding process including:
 - (1) Preparation date;
 - (2) Identification of ingredients (including lot numbers);
 - (3) Quantities of ingredients used;
 - (4) Initials or unique identification of person completing each step;
 - (5) Initials or unique identification of pharmacist verifying each step;
- c. Expiration/beyond-use date;
- d. Internal control number;
- e. Total yield.